

**CYSTEINE HYDROCHLORIDE - cysteine hydrochloride injection, solution**  
HOSPIRA, INC.

Glass Abboject®  
Needleless  
Unit of Use Syringe  
Rx only

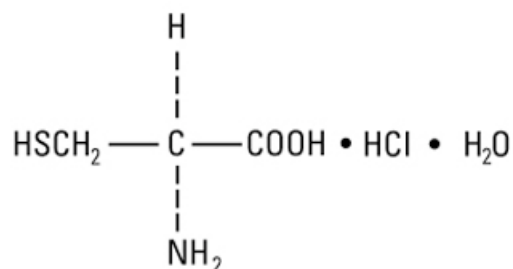
**CAUTION: MUST BE DILUTED**

**DESCRIPTION**

Cysteine Hydrochloride Injection, USP 0.5 gram is a sterile, nonpyrogenic solution containing 0.5 gram of cysteine hydrochloride, monohydrate in 10 mL of water for injection. The pH is 1.3 (1.0 to 2.5). Specific gravity is 1.02; contains 0.285 mMol cysteine/mL. Cysteine is a sulfur-containing amino acid. In premixed solutions of crystalline amino acids, cysteine is relatively unstable over time, eventually converting to insoluble cystine. To avoid such precipitation, Cysteine Hydrochloride Injection, USP is provided as an additive for use with crystalline amino acid solutions immediately prior to administration to the patient.

Cysteine Hydrochloride, USP, monohydrate is chemically designated  $C_3H_7NO_2S \cdot HCl \cdot H_2O$ , a white crystalline powder soluble in water.

It has the following structural formula:



**CLINICAL PHARMACOLOGY**

Cysteine is synthesized from methionine via the trans-sulfuration pathway in the adult, but newborn infants lack the enzyme, cystathionase, necessary to effect this conversion. Therefore, Cysteine Hydrochloride Injection, USP is generally considered to be an essential amino acid in infants.

Metabolism of cysteine produces pyruvate and inorganic sulfate as end products. Cysteine is introduced directly into the pathway of carbohydrate metabolism at the pyruvate stage with all three carbons convertible to glucose. The sulfur is primarily transformed to inorganic sulfate, which is introduced into complex polysaccharides among other structural components.

**INDICATIONS AND USAGE**

Cysteine Hydrochloride Injection, USP 0.5 gram is indicated for **use only after dilution** as an additive to Aminosyn (a crystalline amino acid solution) to meet the intravenous amino acid nutritional requirements of infants receiving total parenteral nutrition.

**CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS**

The contraindications, warnings, precautions and adverse reactions associated with Cysteine Hydrochloride Injection, USP additive are the same as those cited for Aminosyn 5%, given as part of a total parenteral nutrition program, as defined in the accompanying Aminosyn package insert.

**Pregnancy Category C.**

Animal reproduction studies have not been conducted with Cysteine Hydrochloride Injection, USP 0.5 gram. It is also not known whether this additive can cause fetal harm when administered to pregnant women or can affect reproductive capacity. This additive should be given to a pregnant woman only if clearly indicated.

**WARNING:** This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

## OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. SEE WARNINGS and PRECAUTIONS appearing in accompanying Aminosyn package insert.

## DOSAGE AND ADMINISTRATION

Cysteine Hydrochloride Injection, USP 0.5 gram is intended for **use only after dilution** in Aminosyn (a crystalline amino acid solution). Each 10 mL of Cysteine Hydrochloride Injection, USP 0.5 gram should be combined aseptically with 12.5 grams of amino acids, such as that present in 250 mL of Aminosyn 5%. The admixture is then diluted with 250 mL of dextrose 50% or such lesser volume as indicated. Equal volumes of Aminosyn 5% and dextrose 50% produce a final solution which contains Aminosyn 2.5% in dextrose 25%, which is suitable for administration by central venous infusion. Administration of the final admixture should begin within one hour of mixing due to the oxidative degradation of cysteine in the higher pH environment of the amino acid and dextrose admixture. Otherwise, the admixture should be refrigerated immediately and used within 12 hours of the time of mixing. For the recommended rate of administration, see the Aminosyn package insert.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

## HOW SUPPLIED

Cysteine Hydrochloride Injection, USP 0.5 gram (50 mg/mL) is supplied as follows:

List No.	Container
8975	10 mL Glass Abboject <sup>®</sup> Needleless Unit of Use Syringe

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Abboject<sup>®</sup> is a trademark of the Abbott group of companies.

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